



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 11 and 101

[Docket No. FDA-2011-F-0171]

Calorie Labeling of Articles of Food in Vending Machines: Guidance for Industry; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled "Calorie Labeling of Articles of Food in Vending Machines-- Small Entity Compliance Guide." The small entity compliance guide (SECG) is intended to help small entities comply with the final rule entitled "Food Labeling; Calorie Labeling of Articles of Food in Vending Machines."

DATES: Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be

posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2011-F-0171 for "Calorie Labeling of Articles of Food in Vending Machines--Small Entity Compliance Guide." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Office of Nutrition and Food Labeling, Food Labeling and Standards Staff, Center for Food Safety and Applied Nutrition (HFS-305), Food and Drug Administration, 5001 Campus Dr., College Park, MD

20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Ashley N. Rulffes, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of December 1, 2014 (79 FR 71259), we issued a final rule requiring vending machine operators who own or operate 20 or more vending machines, or who voluntarily register to be covered, to provide calorie declarations for those foods sold from vending machines for which the Nutrition Facts label cannot be examined before purchase or for which visible nutrition information is not otherwise provided at the point of purchase (the final rule). Covered vending machine operators must comply with the rule by December 1, 2016. However, in the Federal Register of August 1, 2016 (81 FR 50303), we issued a final rule entitled “Food Labeling; Calorie Labeling of Articles of Food in Vending Machines; Extension of Compliance Date.” This rule provides that the compliance date for type size front-of-pack labeling requirements (§ 101.8(b)(2) (21 CFR 101.8(b)(2))) and calorie disclosure requirements (§ 101.8(c)(2)) for certain gums, mints, and roll candy products in glass-front machines in the final rule published December 1, 2014 (79 FR 71259) is extended to July 26, 2018. The compliance date for all other requirements in the final rule (79 FR 71259) remains December 1, 2016.

We examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612) and determined that the final rule will have a significant

economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121, as amended by Pub. L. 110-28), we are making available the SECG to explain the actions that a small entity must take to comply with the rule.

We are issuing the SECG consistent with our good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents our current thinking on calorie labeling for foods sold in vending machines operated by a person engaged in the business of owning or operating 20 or more vending machines, or a person who voluntarily registers with FDA to be covered by the rule. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This SECG refers to collections of information described in FDA's final rule that published in the Federal Register of December 1, 2014, and that will be effective on December 1, 2016. As stated in the final rule, these collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collections of information in the final rule have been approved under OMB control number 0910-0782. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

III. Electronic Access

Persons with access to the Internet may obtain the SECG at either <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/defa>

ult.htm or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: August 11, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy,

Planning, Legislation and Analysis.

[FR Doc. 2016-19492 Filed: 8/15/2016 8:45 am; Publication Date: 8/16/2016]